Summary of Discussion # 4

- Testing for adventitious agents is part of an integrated program to assure product safety & quality
  - Other elements include procedural & engineering controls & viral clearance
- While powers of detection are limited by sample volume, statistical considerations, and nature of the sample, testing is not the only means of assurance
  - Thus, the inherent limitations of testing have not resulted in reports of administration of contaminated product to recipients
  - Testing has identified a few failures before product release

Summary of Discussion # 4

- New technologies are becoming available and may help improve limits of detection, improve automation, or expand scope of testing
  - New technologies should be carefully evaluated before replacing existing technology in terms of validation, statistical power, and how they fit into the integrated control strategy
  - Near term, PCR mycoplasma tests were under study and may be a practical alternative to cultivational methods for some uses
  - Longer term, other genetic, genomic, and microarray technologies may be available for examination
  - Harmonized approaches to regulatory acceptance are potentially useful, and should be considered where appropriate

Summary of Discussion # 4

- Present testing recommendations seem adequate to assure product quality & safety, but we should remain vigilant for issues and watch the evolution of new technologies
- Interest was expressed in compiling existing information regarding testing for viral contamination of bovine serum (e.g., from USDA efforts), as need to use this reagent will continue for the foreseeable future